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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,693	06/10/2005	Yoshitane Kojima	57A 3727 PCT	6970

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KODA & ANDROLIA
2029 CENTURY PARK EAST
SUITE 1140
LOS ANGELES, CA 90067

EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/538,693	KOJIMA ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the claims on 10 June 2005.

Claims 1-3 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10 June 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The examiner only examined the Abstract of each reference provided in the IDS because this was the only part of the prior art references translated into English.

Drawings

The drawings are objected to because all of the Figures (1-7) are missing labels and, therefore, are not adequately described. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be

necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is ambiguous and poorly written. It is impossible to tell what Applicant is trying to disclose in this abstract because the abstract is indefinite and fails to conform with current U.S. practice. The abstract appears to be a literal translation into English from a foreign document and is replete with grammatical and idiomatic errors. The entire abstract must be rewritten in

such a way that no new matter is introduced and wherein Applicant's true invention is disclosed. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant claims, "A food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc, said food product having a prophylactic effect against diabetes and maintaining health". It appears that Applicant is claiming that the food product has an effect, wherein foods from natural substances and contained in plants and/or yeasts interact with zinc (it is unclear whether Applicant is claiming this happens in the food product itself or when taken internally). It also appears that Applicant is claiming that this food product may be used to maintain health. However, there is no evidence provided in the specification of how this composition may maintain health. Nor is there any description of what type of health is maintained. Is

Applicant maintaining general, overall health of any person or only maintaining the health of diabetics?

Claim 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.O1(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc, said food product having a prophylactic effect against any type of diabetes and maintaining health.

Breadth of the Claims: The claims are broad in that any amount of a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc prophylactic effect

against any type of diabetes and maintaining health. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes feeding ordinary feed, high zinc containing yeast feed and baker's yeast containing feed to mice constituting young, type II diabetes model animals not yet showing the onset of type II diabetes on page 3, "Embodiment I". The specification further describes feeding four week old mice ordinary feed, feed prepared by adding papaya with a high zinc content or feed by adding papaya to ordinary feed until the mice reached eleven weeks of age, wherein the glucose levels were measured and wherein the specification states "Zn/papaya may have the effect of making the elevation of blood sugar levels more gradual and may, thus, have an effect in delaying the onset of diabetes" (See page 4, "Embodiment 2").

The specification envisions that a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc will have utility in humans in by having a prophylactic effect against diabetes and maintaining health.

However, no working examples are provided with regard to a method for preventing diabetes or maintaining health. Furthermore, no working examples are provided that demonstrate the efficacy of a food product having any prophylactic effect against diabetes or maintaining health in humans.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, although advances

have been made to find a suitable murine model to predict human disease, such as type 2 diabetes, (See http://www.scienceblog.com/community/older/2001/B/200111651.html, Reference U), there are no perfected models that mimic type 2 diabetes as the disease appears in humans and there has been no evidence that any type of food or supplement prevents type 2 diabetes in humans or that any type of food or supplement maintains health.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc that has a prophylactic effect against diabetes and maintains health. The Office further notes that while the specification discloses that the claim-designated methods and claim designated compositions will have utility in humans by having a prophylactic effect against diabetes and maintaining health, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc will have utility in humans in by having a prophylactic effect against diabetes and maintaining health to any subject.

It should be noted that at the time of filing of the present application, the art of medicine did not recognize the administration of a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc having a prophylactic effect against diabetes and

maintaining health in humans.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc will have utility in humans in by having a prophylactic effect against diabetes and maintaining health in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to a food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 2 and 3 are not considered to be fully enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "natural substances" in claim 1, line 1 and claim 2, line 2 is a relative term which renders the claim indefinite. The term "natural substances" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The metes and bounds of Claims 1 and 3 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethanopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical as noted in this application. The common name or traditional/ethanopharmacological name may have several different Latin names referring to various genus-species of the plant and it is unclear as to which genus and species Applicant is referring. The lack of clarity renders the claims indefinite since the

resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Applicant may overcome the rejection by placing the genus-species name of "papaya", "maca", "ginkgo", "baker's yeast" and "brewer's yeast" in parentheses after the terms "papaya", "maca", "ginkgo", "baker's yeast" and "brewer's yeast".

The metes and bounds of Claims 1-3 are rendered uncertain by the phrase "a food product containing natural substances (plants such as papaya, maca, ginkgo and the like, and yeasts such as baker's yeast, brewer's yeast and the like) that include zinc at high concentrations", as Claim 1, "A food product containing zinc sources and foods, said foods being originated in natural substances and contained in plants and/or yeasts and interacting with zinc, said food product having a prophylactic effect against diabetes and maintaining health", as Claim 2 and "The food product according to Claims 1 or 2, wherein a mineral source thereof is mineral salts or organic complexes of metals", as Claim 3. The ambiguity arises because Claim 1 could be interpreted to read "A food product comprising papaya, maca and/or ginkgo and further comprising a baker's yeast and/or brewer's yeast, wherein the papaya, maca, ginkgo, baker's yeast and brewer's yeast contain zinc in a high concentration" or Claim 1 could be interpreted to read ""A food product comprising papaya, maca and/or ginkgo, further comprising a baker's yeast and/or brewer's yeast and further comprising zinc in a high concentration" or Claim 1 could be interpreted to read "A food product comprising papaya, maca, ginkgo, a baker's yeast and/or brewer's yeast, wherein the papaya, maca, ginkgo, baker's yeast and brewer's yeast contain zinc in a high concentration" or "A food product comprising papaya, maca, ginkgo, a baker's yeast and/or brewer's yeast and further comprising

zinc in high concentrations". Claim 2 could be interpreted to read "A food product comprising of zinc, plants and/or yeast, wherein the food product is used to treat diabetes and maintain health" or Claim 2 could be interpreted to read "A food product comprising of a zinc source and further comprising an additional food, wherein the zinc source is plants and/or yeast and wherein the food product is used to treat diabetes and maintain health". It appears that Applicant is claiming "The food product of Claim 1 or 2, further comprising a mineral, wherein the mineral is mineral salts or organic metal complexes" as Claim 3. These claims are so difficult to understand, it is difficult to determine Applicant's invention. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 3 recites the limitation "a mineral source thereof" in claim 3. There is insufficient antecedent basis for this limitation in the claim.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1, line 1 and claim 2, line 2 both contain

the term "natural substances". The term "natural substances" infers that these substances are found in nature and do not require manufacturing. Please see MPEP 2105, which states:

"...It is clear from the Supreme Court decision and opinion that the question of whether or U.S.C. 112, Second Paragraph not an invention embraces living matter is irrelevant 2173.05(a) New Terminology to the issue of patentability. The test set down by the 2173.05(b) Relative Terminology Court for patentable subject matter in this area is 2173.05(c) Numerical Ranges and Amounts Limitations whether the living matter is the result of human intervention.

In view of this decision, the Office has issued these guidelines as to how 35 U.S.C. 101 will be interpreted...

(A) "The laws of nature, physical phenomena and abstract ideas" are not patentable subject matter.

(B) A "nonnaturally occurring manufacture or composition of matter — a product of human ingenuity —having a distinctive name, character, [and] use" is patentable subject matter.

(C) "[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of... nature, free to all men and reserved exclusively to none.'"

(D) "[T]he production of articles for use from raw materials prepared by giving to these materials *new forms, qualities, properties, or combinations whether by hand labor or by machinery"* [emphasis added] is a "manufacture" under 35 U.S.C. 101."

Since the invention relates to a food containing natural substances, wherein the natural substance is papaya, maca, ginkgo or yeast and since all of these substances are defined as food, these claims are drawn to products of nature that are not statutory subject matter because they fail to show the "hand of man" in their constitution.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (N, JP 10-036274, Translation provided herein).

Yoshida teaches a metal salt mixture from papaya for ingestion. Since the claim reads in such a manner that papaya naturally contains high levels of zinc, Yoshida teaches the invention of Claims 1-3.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process.

Therefore, the reference anticipates the claimed subject matter.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujii (O, JP 2000316528 A, Translation provided herein).

Fujii teaches a nutrition supplement food comprising yeast containing zinc and maca, which may be used to treat diabetes-mellitus (See abstract and page 3 of 3 of the translation).

Therefore, the reference anticipates the claimed subject matter.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Dou et al. (V, Translation of Abstract Provided).

Dou teaches a nutrient health-care soybean curd coagulation comprising ginkgo powder and zinc gluconate, wherein the soybean curd posseses dietary health-care function.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, as a prophylactic for diabetes, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process.

Therefore, the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
August 30, 2006

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER